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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/359,260	07/22/1999	ROBERT L. CAMPBELL	P3250	2590

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EXAMINER

FRIEND, TOMAS H F

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 12/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/359,260

Applicant(s)

CAMPBELL ET AL.

Examiner

Tomas Friend

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 74 and 76-95 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 74 and 76-95 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 16.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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Detailed Action

Change of Art Unit Designation

Please note: The Art Unit location of this application in the PTO has changed from Art Unit 1627 to Art Unit 1639. To aid in matching papers to this application, all further correspondence regarding this application should be directed to **Group Art Unit 1639**.

Change of Examiner's Name

The name of the examiner of this application has changed from Thomas Prasthofer to Tomas Friend.

Status of the Application – Not in Compliance with Sequence Rules

Applicant's amendment and Raw Sequence Listing with CRF submitted on 13 September 2002 (Paper Nos. 18 and 19) have been received but the application is not in conformance with the sequence rules for the following reasons: Applicants have not amended the specification to identify all applicable sequences by their sequence I.D. Nos. A complete reply to this office action must include the necessary corrections to the specification to ensure that the application is in compliance with the sequence rules.

Status of the Claims

Claims 74 and 76-95 are pending and examined in their merits.

Withdrawn Rejections

1. The rejection of claim 76 under 35 U.S.C. 112, second paragraph, over what distinguishes between a "*parameter*" and a "*whole molecule parameter*" is withdrawn in response to applicants' amendment.

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2. The rejection of claim 81 under 35 U.S.C. 112, second paragraph, over “*isomers*” is withdrawn in response to applicants’ amendment.
3. The rejection of claims 74 and 77 over the term “*test requirement*” is withdrawn.

Maintained Rejections

The statutory basis for each of the following rejections may be found in a prior office action.

Maintained Rejections – 35 U.S.C. 112, second paragraph

4. Claims 74, 76-78, 80-86, and 91 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 74, 76, 80, 83, 84, and 86 remain rejected over the metes and bounds of the term “*whole molecule parameter*.”

Applicants argue that the term “*whole molecule parameter*” is definite and that claims have been amended (presumably in such a way as to overcome the rejection). Applicants’ arguments have been fully considered but they are not persuasive. Applicants cited three portions of the present specification in support of the argument that the term “*whole molecule parameter*” is definite. Page 28, lines 2-4 indicates that a “*whole molecule parameter*” is “*a value that characterizes a molecule irrespective of the arrangement of its constitutive atoms.*” Page 28, lines 11-26 describes a “*sequence specific parameter*” and does not address the metes and bounds of the term “*whole molecule parameter*.” Page 11, lines 12-14, includes the term “*sequence-specific parameter(s)*” but otherwise is unrelated to the present rejection. The claims, as amended, recite “*whole molecule parameter*.”

B. Claims 74 and 82 remain rejected over the term “*space filling technique*,” which is not defined by the specification in such a way that one of ordinary skill in the art would be able to determine the metes and bounds of the claimed invention.

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Applicants point to page 19, lines 17-19, “*where ‘space-filling design’ is expressly defined.*” The sentence beginning on page 19, line 17 reads: “*The term ‘space-filling design’ as used herein is intended to be construed broadly and includes all such techniques known to those skilled in the art.*” No art recognized definition for the term is provided in the specification and no such definition is of record. One skilled in the art would assume that the specific examples in the specification are encompassed by “*space filling design*” in the rejected claims, but one would not know what else is encompassed. Applicants’ amendment to the rejected claims to replace “*technique*” with “*design*” does not overcome the rejection. Please note applicants’ argument that the terms “*technique*” and “*design*” are to be used interchangeably.

Applicants have not addressed the specific question raised by the examiner with respect to “*space-filling design.*” If a first library were all possible pentamers and the second library were all possible tetramers with glycine at the N-terminus, for example, would the second library have been selected based upon a space-filling design?

D. Claims 74, 76, and 80 remain rejected over the metes and bounds of the phrase “*determining a relationship.*”

Applicants argue that the phrase is found in 500 issued patents so one skilled in the art would recognize the metes and bounds of the phrase. Applicants’ argument has been fully considered but it is not persuasive. Please note that each patent is examined on its own merits. Applicants have in no way implied or stated that the phrase “*determining a relationship*” as used in the present application is to be interpreted in the same way(s) as the term is used in 500 issued patents. Applicants have not responded to the statement in the rejection that the “*relationship*” is relative term (i.e. the degree and/or nature of relationship to be encompassed by the claim is not clear). Applicants have not responded to the request for clarification but have merely stated that the term is found in issued patents. Applicants have asserted that “*determining a relationship*” is a well-recognized term of art but applicants have not stated what relationships are to be encompassed by the claims as they apply to the present invention.

E. Claim 74 remains rejected over the metes and bounds of the second peptide library based arising from the limitation that that the plurality of second test peptides are “*expected*” to provide an indicia of an activity, based upon a relationship.

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Applicants argue that the term “*expected*” is “*relationship dependent*” and that the “*exclusion and inclusion criterion for selection/identification would be within the purview of the end-user.*” Applicants provide an example in which “*the relationship may be between molecular weight/pI/sequence length and protein/expression.*”

Applicants’ arguments have been fully considered but they are not persuasive. Applicants’ argument appears to suggest that the metes and bounds of the rejected claim are to be determined by one wishing to use the claimed invention. Furthermore, applicants’ argument appears to be incompatible with claim 74 as amended. Claim 74 now recites that the relationship must be determined between at least two parameters (one of which is sequence specific) and a first indicia of activity. Applicants argues that “*the relationship may be between molecular weight/pI/sequence length and protein production/expression.*” Since many different sequences can have the same sequence length, the same molecular weight, or the same pI, it is not clear that any of these parameters are sequence specific.

F. Claims 74, 76-78, 80, and 91 remain rejected over the term “*indicia*.”

Applicants argue that applicants are using the plain definition (i.e. according to The American heritage College Dictionary, 3rd ed. (1997)) . Applicants also cite the abstract and page 260 of Cho et al., J. Chem. Inf. Comput. Sci. (1998)38:259-268.

Applicants’ arguments have been fully considered but they are not persuasive. The Cho et al. reference does not recite the word “*indicia*” in the abstract or on page 260, column 2. The reference does recite that pentapeptides “*can be described either by topological indices*” (i.e. plural of index). With regard to the dictionary definition of “*indicia*,” “Webster’s New World Dictionary, Third College Edition” (1988) Simon & Schuster, Inc. defines “*indicia*” as the plural of the noun “*indiciu*m” meaning “*a characteristic mark or token.*” Given the different “*plain*” definitions of “*indicia*” and the possible inclusion of “*indices*” as being encompassed by the term, the rejection is maintained.

H. Claims 77 and 78 remain rejected over how a “*range*” of “*indicia*” (values?) may be “*qualified*” (i.e. what it means for a range of indicia to be qualified).

Applicants argue that page 26, line 32 to page 27, line 10 of the specification outline and exemplify ranges and the determination of quantitative and qualitative measures.

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Applicants' argument has been fully considered but it is not persuasive. The cited passage does not make mention of "*qualifying*" a range of indicia.

I. Claim 82 remains rejected over the term "*isomers*" having a definition that is repugnant to the usual meaning of that term.

Applicants argue that page 45, lines 7-12 of the specification "*exemplifies the idea that compound isomers have the same chemical formula or amino acid composition.*" Applicants cite a web cite which provides a definition of "*isomers*" in agreement with (Zumdahl, Steven S., "Chemistry", 4th ed., Houghton Mifflin Company, 1997).

Applicants' arguments have been fully considered and they appear to support the rejection of record in the sense that the argument presents a definition of "*isomers*" that is incompatible with the definition on page 48 of the specification. The presence of another passage in the specification which "*exemplifies the idea that compound isomers have the same chemical formula or amino acid composition*" does not overcome the rejection because two peptides with the same amino acid composition are not necessarily isomers according to the art recognized definition (e.g. two octapeptides comprising the same amino acids but id different sequences are not generally referred to as isomers).

J. Claim 82 remains rejected over the term "*isomers*" as defined in the specification as "*the group of compounds sharing common global characteristics*" wherein one skilled in the art would not know the metes and bounds of "*global characteristics*."

Applicants argue that U.S. Patent 6,184,329, column 39, Table 3, heading, includes the term "*global characteristics*" and is therefor an art recognized term. Applicants' argument has been fully considered but it is not persuasive. The examiner notes that the text of the patent cited by applicants is not available to the examiner nor, has a copy of the patent been provided by the applicants. It is not clear how the use of the term "*global characteristics*" in a U.S. patent can be interpreted as evidence that the term "*global characteristics*" is an art recognized term.

Applicants have not argued a particular meaning or metes and bounds for the term.

K. In claim 85, it is not clear if applicant intended to recite "*whole molecule parameter*" rather than "*parameter*." If the claim is recited applicant's intended language, it is not clear what distinguishes a "*parameter*" from a "*whole molecule parameter*." Clarification is requested.

Maintained Rejections – 35 U.S.C. 102

5. Claims 74, 81, 87- 90, and 94 remain rejected under 35 U.S.C. 102(b) as being anticipated by Tenson et al., The Journal of Biological Chemistry, 272:17425-17430, 1997.

Applicants argue that the rejection of claims 74, 81, 87- 90, and 94 was withdrawn in response to applicants' amendment of claim 74 to include the limitations of original claim 75 (space-filling design). The examiner notes that claims 74, 81, 87- 90, and 94 were rejected in the previous office action mailed 15 January 2002 (Paper No. 13).

Applicants argue that "*space filling design*" is expressly defined in the specification. Page 19, line 17 of the present specification reads: "*The term 'space-filling design' as used herein is intended to be construed broadly and includes all such techniques known to those skilled in the art.*" In light of applicants' argument and the direction in the specification to interpret the term "*space filling design*" broadly, the examiner maintains that the technique (or design) used by Tenson et al. is encompassed by "*space filling design.*"

Applicants argue that "*from the enumerated list of examples, relationships between a dependent variable and one or more independent variables are exploited. No such relationships between a dependent and one or more independent variables are exploited in the cited reference. Therefore, no space-filling design is taught or suggested in said reference.*"

Applicants' argument has been fully considered but it is not persuasive. Applicants appear to be arguing limitations that are not recited in the rejected claims. There are no limitations in the rejected claims nor is there any definition of "*space-filling design*" in the specification that requires dependent and one or more independent variables. Additionally, it is not clear from applicants' arguments, what the variables are to be independent or dependent from.

As amended, the rejected claims recite "...*determining a relationship between the first indicia of the activity and at least two parameters of the plurality of first test peptides, wherein one parameter is a whole molecule parameter and an additional parameter is a sequence specific parameter...*" With regard to the Tenson et al. reference, the ability of cells to grow in the presence but not the absence of IPTG can be related to peptide length (sequence independent) and an N-terminal methionine (sequence dependent). The second library was a 5-codon library that

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was designed to express all possible pentapeptides (i.e. a space filling technique was used). The examiner is not relying upon inherency of space-filling designs in the method disclosed by Tenson et al. Rather, the examiner maintains that the method disclosed by Tenson et al. for making a second peptide library qualifies as a space filling design according to the present claims.

6. Claims 74, 92, 94, and 95 remain rejected under 35 U.S.C. 102(b) as being anticipated by Ostrem et al, Biochemistry 37:1053-1059 (1998).

Applicants argue that the rejection of claims 74, 92, 94, and 95 was withdrawn in response to applicants' amendment of claim 74 to include the limitations of original claim 75 (space-filling design). The examiner notes that claims 74, 92, 94, and 95 were rejected in the previous office action mailed 15 January 2002 (Paper No. 13).

Applicants argue that "*space filling design*" is expressly defined in the specification. Page 19, line 17 of the present specification reads: "*The term 'space-filling design' as used herein is intended to be construed broadly and includes all such techniques known to those skilled in the art.*" In light of applicants' argument and the direction in the specification to interpret the term "*space filling design*" broadly, the examiner maintains that the technique (or design) used by Ostrem et al. is encompassed by "*space filling design*."

Applicants argue that "*from the enumerated list of examples, relationships between a dependent variable and one or more independent variables are exploited. No such relationships between a dependent and one or more independent variables are exploited in the cited reference. Therefore, no space-filling design is taught or suggested in said reference.*"

Applicants' argument has been fully considered but it is not persuasive. Applicants appear to be arguing limitations that are not recited in the rejected claims. There are no limitations in the rejected claims nor is there any definition of "*space-filling design*" in the specification that requires dependent and one or more independent variables. Additionally, it is not clear from applicants' arguments, what the variables are to be independent or dependent from.

As amended, the rejected claims recite "...*determining a relationship between the first indicia of the activity and at least two parameters of the plurality of first test peptides, wherein one parameter is a whole molecule parameter and an additional parameter is a sequence specific*

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parameter...” With regard to the Ostrem et al. reference, a peptide length of 8 amino acids reads (sequence independent parameter) and the presence of a YIR sequence (sequence dependent parameter) were determined to relate to the measured first indicia of an activity. All resynthesized peptides of the second peptide library included specific amino acid motifs (the selection of peptides as well as modified peptides including the YIR sequence was a “*space-filling technique*” because the structures around the YIR sequence were replaced by a variety of moieties). The examiner is not relying upon inherency of space-filling designs in the method disclosed by Ostrem et al. Rather, the examiner maintains that the method disclosed by Ostrem et al. for making a second peptide library qualifies as a specie filling design according to the present claims.

New Grounds of Rejection

The statutory basis for each of the following rejections not found below may be found in a prior office action.

New Grounds of Rejection – 35 U.S.C. 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 74 and 76-95 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention (New Matter).

A. Claim 76 has been amended to recite a formula wherein X_{ij} denotes a whole molecule parameter as opposed to a parameter. It appears that there is no support in the specification for such an amendment. In accordance with MPEP 714.02, applicant should specifically point out where support can be found for any amendment made to the disclosure.

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B. Claim 81 has been amended to recite “...wherein said determining first indicia step is preceded by the step of defining a first test peptide library...” It appears that there is no support in the specification for such an amendment. In accordance with MPEP 714.02, applicant should specifically point out where support can be found for any amendment made to the disclosure.

C. Claim 83 has been amended to recite the limitation that said whole molecule parameter is selected from the group consisting of total charge, molecular weight, isoelectric point, and total dipole moment and eliminating the limitation that the at least one parameter is selected from the group consisting of isotropic surface area, electronic charge index, and hydrophobicity. It appears that there is no support in the specification for such an amendment. In accordance with MPEP 714.02, applicant should specifically point out where support can be found for any amendment made to the disclosure.

D. Claim 84 has been amended to recite specific simultaneous limitations for both whole molecule parameters and sequence specific parameters. It appears that there is no support in the specification for such an amendment. In accordance with MPEP 714.02, applicant should specifically point out where support can be found for any amendment made to the disclosure.

E. Claim 74 has been amended to recite determining a relationship between the first indicia of the activity and at least two parameters wherein one parameter is a whole molecule parameter and at least one other parameter is a sequence-specific parameter. Support for such a limitation cannot be found in the specification as filed. In accordance with MPEP 714.02, applicant should specifically point out where support can be found for any amendment made to the disclosure.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Tomas Friend** at telephone number **(703) 308-4548**. The examiner's normal schedule is four, ten-hour days per week including Saturdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2742.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist at (703) 308-1235.

Tomas Friend, Ph.D.
25 November 2002



ANDREW WANG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600